

(2) May be direct or indirect and through debt, equity or other means.

(3) *Exceptions.* The following are not ownership or investment interests for the purposes of this section:

(i) An ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act.

(ii) An interest in an applicable manufacturer or applicable group purchasing organization that arises from a retirement plan offered by the applicable manufacturer or applicable group purchasing organization to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that applicable manufacturer or applicable group purchasing organization.

(iii) Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity.

(iv) An unsecured loan subordinated to a credit facility.

(v) An ownership or investment interest if an applicable manufacturer or applicable group purchasing organization did not know, as defined in this section, about such ownership or investment interest.

Payment or other transfer of value means a transfer of anything of value.

Physician has the same meaning given that term in section 1861(r) of the Act.

Related to a covered drug, device, biological, or medical supply means that a payment or other transfer of value is made in reference to or in connection with one or more covered drugs, devices, biologicals, or medical supplies.

Research includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.

Third party means another individual or entity, regardless of whether such individual or entity is operating in the United States.

§ 403.904 Reports of payments or other transfers of value to covered recipients.

(a) *General rule.* (1) Direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient during the preceding calendar year, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient during the preceding calendar year, must be reported by the applicable manufacturer to CMS on an annual basis.

(2) For CY 2013, only payments or other transfers of value made on or after August 1, 2013 must be reported to CMS.

(b) *Limitations.* Certain limitations on reporting apply in the following circumstances:

(1) Applicable manufacturers for whom total (gross) revenues from covered drugs, devices, biologicals, or medical supplies constituted less than 10 percent of total (gross) revenue during the fiscal year preceding the reporting year are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals or medical supplies.

(2) Applicable manufacturers under paragraph (2) of the definition in § 403.902 are only required to report payments or other transfers of value that are related to a covered drug, device, biological, or medical supply for which they provided assistance or support to an applicable manufacturer under paragraph (1) of the definition.

(3) Applicable manufacturers under either paragraph (1) or (2) of the definition in § 403.902 that have separate operating divisions that do not manufacture any covered drugs, devices, biologicals, or medical supplies (for example, animal health divisions) are only required to report payments to covered recipients related to the activities of these separate divisions if those payments or other transfers of value are related to a covered drug, device, biological, or medical supply. This includes reporting of payments or other transfers of value that are related to covered drugs, devices,

biologicals, or medical supplies made by applicable manufacturers to covered recipients through these operating divisions.

(4) Applicable manufacturers that do not manufacture a covered drug, device, biological, or medical supply except when under a written agreement to manufacture the covered drug, device, biological, or medical supply for another entity, do not hold the FDA approval, licensure, or clearance for the covered drug, device, biological, or medical supply, and are not involved in the sale, marketing, or distribution of the product, are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals, or medical supplies.

(c) *Required information to report.* A report must contain all of the following information for each payment or other transfer of value:

(1) *Name of the covered recipient.* For physician covered recipients, the name must be as listed in the National Plan & Provider Enumeration System (if applicable) and include first and last name, middle initial, and suffix (for all that apply).

(2) *Address of the covered recipient.* Primary business address of the covered recipient, including all the following:

- (i) Street address.
- (ii) Suite or office number (if applicable).
- (iii) City.
- (iv) State.
- (v) ZIP code.

(3) *Identifiers for physician covered recipients.* In the case of a covered recipient who is a physician, the following identifiers:

- (i) The specialty.
- (ii) National Provider Identifier (if applicable and as listed in the NPPES). If a National Provider Identifier cannot be identified for a physician, the field may be left blank, indicating that the applicable manufacturer could not find one.
- (iii) State professional license number(s) (for at least one State where the physician maintains a license), and the State(s) in which the license is held.

(4) *Amount of payment or other transfer of value.* A payment or other transfer of

value made to a group of covered recipients should be distributed appropriately among the individual covered recipients who requested the payment, on whose behalf the payment was made, or who are intended to benefit from the payment or other transfer of value.

(5) *Date of payment or transfer of value.* The date of each payment or other transfer of value.

(i) For payments or other transfers of value made over multiple dates (rather than as a lump sum), applicable manufacturers may choose whether to report each payment or other transfer of value as separate line item using the dates the payments or other transfers of value were each made, or as a single line item for the total payment or other transfer of value using the first payment date as the reported date.

(ii) For small payments or other transfers of value reported as a single line item, applicable manufacturers must report the date that the first bundled small payment or other transfer of value was provided to the covered recipient.

(6) *Form of payment or transfer of value.* The form of each payment or other transfer of value, as described in paragraph (d) of this section.

(7) *Nature of payment or transfer of value.* The nature of each payment or other transfer of value, as described in paragraph (e) of this section.

(8) *Related covered drug, device, biological or medical supply.* The name(s) of the related covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply. Applicable manufacturers may report up to five covered drugs, devices, biologicals or medical supplies related to each payment or other transfer of value. If the payment or other transfer of value was related to more than five covered drugs, devices, biologicals, or medical supplies, the applicable manufacturer should report the five covered drugs, devices, biologicals, or medical supplies that were most closely related to the payment or other transfer of value.

(i) For drugs and biologicals, applicable manufacturers must report the

name under which the drug or biological is or was marketed and the relevant National Drug Code(s), if any. If the marketed name has not yet been selected, the applicable manufacturer must indicate the name registered on clinicaltrials.gov.

(ii) For devices and medical supplies, applicable manufacturers must report at least one of the following:

(A) The name under which the device or medical supply is or was marketed.

(B) The therapeutic area or product category for the device or medical supply.

(iii) If the payment or other transfer of value is not related to a covered drug, device, biological or medical supply, but is related to a specific non-covered product, applicable manufacturers must indicate “non-covered product.”

(iv) If the payment or other transfer of value is not related to any drug, device, biological, or medical supply (covered or not), applicable manufacturers must indicate “none.”

(v) If the payment or other transfer of value is related to at least one covered drug, device, biological, and medical supply and at least one non-covered drug, device, biological, or medical supply, applicable manufacturers must report the name(s) of the covered drug, device, biological or medical supply (as required by paragraphs (c)(8)(i) and (ii) of this section) and may indicate “non-covered products” in addition.

(9) *Eligibility for delayed publication.* Applicable manufacturers must indicate whether a payment or other transfer of value is eligible for delayed publication, as described in § 403.910.

(10) *Payments to third parties.* (i) If the payment or other transfer of value was provided to a third party at the request of or designated on behalf of a covered recipient, the payment or transfer of value must be reported in the name of that covered recipient.

(ii) If the payment or other transfer of value was provided to a third party at the request of or designated on behalf of a covered recipient, the name of the entity that received the payment or other transfer of value (if made to an entity) or indicate “individual” (if made to an individual). If a covered recipient performed a service, but nei-

ther accepted the offered payment or other transfer of value nor requested that it be made to a third party, the applicable manufacturer is not required to report the offered payment or other transfer of value unless the applicable manufacturer nonetheless provided it to a third party and designated such payment or other transfer of value as having been provided on behalf of the covered recipient.

(11) *Payments or transfers of value to physician owners or investors.* Must indicate whether the payment or other transfer of value was provided to a physician or the immediate family of the physician who holds an ownership or investment interest (as defined § 403.902) in the applicable manufacturer.

(12) *Additional information or context for payment or transfer of value.* May provide a statement with additional context for the payment or other transfer of value.

(d) *Reporting the form of payment or other transfer of value.* An applicable manufacturer must report each payment or transfer of value, or separable part of that payment or transfer of value, as taking one of the following forms of payment that best describes the form of the payment or other transfer of value, or separable part of that payment or other transfer of value.

(1) Cash or cash equivalent.

(2) In-kind items or services.

(3) Stock, stock option, or any other ownership interest.

(4) Dividend, profit or other return on investment.

(e) *Reporting the nature of the payment or other transfer of value.* (1) *General rule.* The categories describing the nature of a payment or other transfer of value are mutually exclusive for the purposes of reporting under subpart I of this part.

(2) *Rules for categorizing natures of payment.* An applicable manufacturer must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, with one of the categories listed in paragraphs (e)(2)(i) through (xvii) of this section, using the designation that best describes the nature of the payment or other transfer of value, or separable

part of that payment or other transfer of value. If a payment or other transfer of value could reasonably be considered as falling within more than one category, the applicable manufacturer should select one category that it deems to most accurately describe the nature of the payment or transfer of value.

- (i) Consulting fee.
- (ii) Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.
- (iii) Honoraria.
- (iv) Gift.
- (v) Entertainment.
- (vi) Food and beverage.
- (vii) Travel and lodging (including the specified destinations).
- (viii) Education.
- (ix) Research.
- (x) Charitable contribution.
- (xi) Royalty or license.
- (xii) Current or prospective ownership or investment interest.
- (xiii) Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.
- (xiv) Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.
- (xv) Grant.
- (xvi) Space rental or facility fees (teaching hospital only).

(f) *Special rules for research payments.* All payments or other transfers of value made in connection with an activity that meets the definition of research in this section and that are subject to a written agreement, a research protocol, or both, must be reported under these special rules.

(1) Research-related payments or other transfers of value to covered recipients (either physicians or teaching hospitals), including research-related payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported to CMS separately from other payments or transfers of value, and must include the following information (in lieu of the information required by § 403.904(c)):

(i) Name of the research institution, individual or entity receiving the payment or other transfer of value.

(A) If paid to a physician covered recipient, all of the following must be provided:

- (1) The physician's name as listed in the NPPES (if applicable).
- (2) National Provider Identifier.
- (3) State professional license number(s) (for at least one State where the physician maintains a license) and State(s) in which the license is held.
- (4) Specialty.
- (5) Primary business address of the physician(s).

(B) If paid to a teaching hospital covered recipient, list the name and primary business address of teaching hospital.

(C) If paid to a non-covered recipient (such as a non-teaching hospital or clinic), list the name and primary business address of the entity.

(ii) Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both.

- (iii) Name of the research study.
- (iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section) and for drugs and biologicals, the relevant National Drug Code(s), if any.
- (v) Information about each physician covered recipient principal investigator (if applicable) set forth in paragraph (f)(1)(i)(A) of this section.

(vi) Contextual information for research (optional).

(vii) ClinicalTrials.gov identifier (optional).

(2) For pre-clinical studies (before any human studies have begun), only report the following information:

- (i) Research entity name (as required in paragraph (f)(1)(i) of this section).
- (ii) Total amount of payment (as required in paragraph (f)(1)(ii) of this section).
- (iii) Principal investigator(s) (as required in paragraph (f)(1)(v) of this section).

(g) *Special rules for payments or other transfers of value related to continuing education programs.* (1) Payments or other transfers of value provided as

compensation for speaking at a continuing education program are not required to be reported, if all of the following conditions are met:

(i) The event at which the covered recipient is speaking meets the accreditation or certification requirements and standards for continuing education of one of the following:

(A) The Accreditation Council for Continuing Medical Education.

(B) The American Academy of Family Physicians.

(C) The American Dental Association's Continuing Education Recognition Program.

(D) The American Medical Association.

(E) The American Osteopathic Association.

(ii) The applicable manufacturer does not pay the covered recipient speaker directly.

(iii) The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

(2) Payments or other transfers of value that do not meet all of the requirements in paragraph (g)(1) must be reported as required by this section.

(i) Payments or other transfers of value that meet the requirements in paragraph (g)(1)(i) of this section, but not also (g)(1)(ii) or (g)(1)(iii) of this section or both, must be reported under the nature of payment category "Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program."

(ii) Payments or other transfers of value that do not meet the requirements in paragraph (g)(1)(i) of this section should be reported under the nature of payment category "Compensation for serving as a faculty or as a speaker for a unaccredited and non-certified continuing education program."

(iii) Payments or other transfers of value for speaking engagements not related to medical education should be reported under the nature of payment category "Compensation for services other than consulting, including serv-

ing as a speaker at an event other than a continuing education program."

(h) *Special rules for reporting food and beverage.* (1) When allocating the cost of food and beverage among covered recipients in a group setting where the cost of each individual covered recipient's meal is not separately identifiable, such as a platter provided to physicians in a group practice setting, applicable manufacturers must calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal (including both covered recipients and non-covered recipients, such as office staff). The per person value of the meal must be reported as a payment or other transfer of value only for covered recipients who actually partook in the food or beverage.

(2) Applicable manufacturers are not required to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or similar large-scale event.

(i) *Exclusions from reporting.* The following are excluded from the reporting requirements specified in this section:

(1) Indirect payments or other transfers of value (as defined in § 403.902), where the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in § 403.902) the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.

(2)(i) For CY 2013, payments or other transfers of value less than \$10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds \$100 in a calendar year.

(ii) For CY 2014 and subsequent calendar years, to determine if transfers of value are excluded under this section, the dollar amounts specified in paragraph (i)(2)(i) of this section must be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year. CMS will

publish the values for the next reporting year 90 days before the beginning of the reporting year.

(iii) Payments or other transfers of value of less than \$10 in CY 2013 (or less than the amount described in paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years) provided at large-scale conferences and similar large-scale events, as well as events open to the public, do not need to be reported nor included for purposes of the \$100 aggregate threshold in CY 2013 (or the aggregate threshold calculated in accordance paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years), even if the aggregate total for a covered recipient exceeds the aggregate threshold for the calendar year.

(iv) When reporting payments or other transfers of value under the \$10 threshold for CY 2013 (or under the amount described in paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years) for covered recipients that exceed the aggregate threshold for the reporting year, applicable manufacturers may (but are not required to) report all small payments to a particular covered recipient that fall within the same nature of payment category as a single payment or other transfer of value.

(3) Product samples, including coupons and vouchers that can be used by a patient to obtain samples, which are not intended to be sold and are intended for patient use.

(4) Educational materials and items that directly benefit patients or are intended to be used by or with patients, including the value of an applicable manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply.

(5) The loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient.

(6) Items or services provided under a contractual warranty (including service or maintenance agreements), whether or not the warranty period has

expired, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(7) A transfer of anything of value to a physician covered recipient when the covered recipient is a patient, research subject or participant in data collection for research, and not acting in the professional capacity of a covered recipient.

(8) Discounts, including rebates.

(9) In-kind items used for the provision of charity care.

(10) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.

(11) In the case of an applicable manufacturer who offers a self-insured plan or directly reimburses for healthcare expenses, payments for the provision of health care to employees and their families.

(12) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.

(13) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration.

(14) A payment or transfer of value to a covered recipient if the payment or transfer of value is made solely in the context of a personal, non-business-related relationship.

§ 403.906 Reports of physician ownership and investment interests.

(a) *General rule.* (1) Each applicable manufacturer and applicable group purchasing organization must report to CMS on an annual basis all ownership and investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding calendar year.